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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,565	06/11/2007	Suresh Pareek	11336.1026USWO	8564
52835 7590 11/22/2010 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902				
EXAMINER				
CHAN, HENG M				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/590,565

Applicant(s)

PAREEK ET AL.

Examiner

HENG M. CHAN

Art Unit

1728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

Applicant's amendments and remarks filed 9/7/2010 have been acknowledged.
Claims 1-14 are pending. Claims 10 and 14 are withdrawn from consideration.

Claim Objections

1. Claim 6 is objected to because "at least one of non-soluble additives" should be changed to "at least one non-soluble additive" to avoid lack of antecedent basis issues. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. The rejection of claim 6 under 35 USC 112, 2nd paragraph has been withdrawn as a result of Applicants' amendments and further consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2002/01320006 to Sue et al.

Regarding claim 1, Sue et al. teach a color coat comprising a polymer, e.g. hydroxypropyl methylcellulose, and a flavoring agent, e.g. peppermint oil or other flavorant ([0088-89]). The lack of mention of a sweetening agent is understood that the composition does not comprise a sweetening agent. The color coat itself or the composition of the color coat prior to application reads on the claimed ready mix flavored composition. The color coat composition offers a more palatable tablet ([0088]) and the flavoring agent masks unpleasant taste of a solid core of a pharmaceutical oral solid dosage form at least to some degree. The limitation "for film coating of pharmaceutical oral solid dosage form" is a recitation of intended use and does not necessarily impart structural or compositional limitations on the composition. In case it does, Sue et al. teach that all coatings can be applied using conventional film coating technology well known in the pharmaceutical industry, for example, film-coating ([0036]), onto a pharmaceutically active tablet core 2 (abstract; Fig. 1). That is, the composition can be used for film coating of pharmaceutical oral solid dosage form.

Regarding claims 2 and 11, Sue et al. teach that the color coat comprises hydroxypropyl methylcellulose ([0089]), a water soluble hydrophilic polymer.

Regarding claims 3 and 12, Sue et al. teach that the color coat comprises ethylcellulose ([0089]), a water insoluble hydrophobic polymer.

Regarding claims 4 and 13, Sue et al. teach that the color coat comprises ethylcellulose in addition to hydroxypropyl methylcellulose ([0089]), a combination of a water soluble hydrophilic polymer and a water insoluble hydrophobic polymer.

Regarding claim 5, Sue et al. teach peppermint oil as a flavoring agent ([0089]). This flavoring agent is volatile.

Regarding claim 6, Sue et al. teach that the color coat comprises a plasticizer, e.g. polyvinyl alcohol, a colorant, e.g. titanium dioxide, and a non-soluble additive other than the colorant, e.g. ethylcellulose ([0089-90]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sue et al. as applied to claim 1 above, in view of US 5,098,715 to McCabe et al.

Regarding claims 7-9, Sue et al. teach that the color coat comprises a polymer, e.g. hydroxypropyl methylcellulose ([0089]), a plasticizer, and at least one non-soluble additive such as a colorant ([0090]).

Sue et al. do not expressly teach that the polymer comprises the claimed amounts of polymer, flavoring agent, plasticizer, and non-soluble additive selected from a group consisting of a colorant, a detackifier and an opacifying agent.

McCabe et al., who also relate to flavored film-coated tablet, teach using about 5 to 95% w/w hydroxypropyl methylcellulose, 0 to about 25% w/w polyethylene glycol (a plasticizer), 0 to about 20% w/w titanium dioxide or colorant, and 2.0% w/w natural and artificial peppermint flavor, based on the total weight of the coating composition (column 4, lines 41-55; Example 2).

It would have been obvious to one of ordinary skill in the art at time of invention to have arrived at the claimed amounts of polymer, flavoring agent, plasticizer, and non-soluble additives such as colorants in the composition of Sue et al., motivated by the fact that McCabe et al. teach that the preferred flavoring amount is readily determined by balancing the goal of adding an amount sufficient to mask the core tablet taste and provide a distinct, characteristic and pleasing taste, and the goal of keeping the tablet from being too much like a candy or mint product. The desired strength of the flavoring may vary depending on the type of tablet and the intended recipients and the identity of the flavoring (column 5, lines 11-19). The skilled artisan would have therefore optimized the amounts of the ingredients in the composition in order to achieve the desired strength of flavoring.

Response to Arguments

5. Applicant's arguments filed 9/7/2010 have been fully considered but they are not persuasive.

Regarding claims 1-6, Applicants argued that Sue does not disclose a ready mix flavored composition that is a ready-to-use composition, which includes all components

for coating a solid core of a pharmaceutical oral solid dosage form, can be applied to a solid core of the dosage form when reconstituted in a solvent, and masks unpleasant taste of the solid core. The Examiner respectfully disagrees. First of all, claim 1 contains the word "comprising" which by no means limits the composition to only the recited elements. The claims do not necessarily include *all* components for coating a solid core of a pharmaceutical oral solid dosage form as asserted by the Applicants. Second of all, the term "ready mix" is not clearly defined in the specification or the claims and so Applicants' interpretation that the claimed composition "can be applied to a solid core of the dosage form when reconstituted in a solvent" is not required by the claims. Applicants further argued that Sue discloses coating formulations such as coatings #1-4 and no examples in which the color coat can be used alone as a ready mix composition. However, the Examiner did not rely on all four coatings and one skilled in the art would not have been limited to any specific embodiment or example of the reference. Rather, the Examiner found that all of the claimed ingredients are present in the color coat alone and concluded that the color coat composition is just as ready-to-use (i.e. ready mix) as the claimed invention based on its chemical makeup. If Applicants wish to distinguish the claimed invention from the prior art, structural and further chemical differences between the two must be claimed. Finally, the flavoring agent in the color coat composition, e.g. peppermint oil, does not only mask odor but also the unpleasant taste of the solid core because Sue teaches that the color coat offers a more palatable tablet ([0088]). Sue thus teaches the claimed composition.

Regarding claims 7-9, Applicants attacked McCabe individually that McCabe discloses a flavored thin film coating containing a sweetening agent in addition to a flavoring agent and further discloses that a coating dispersion formulation is prepared by suspending the components in water before coating and thus fails to disclose the claimed ready mix flavored composition. In addition, McCabe is silent that the coating composition including the flavoring agent alone can mask the unpleasant taste of the active ingredient. However, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Examiner has addressed the limitations reciting "but no sweetening agent," "ready mix," and "masks unpleasant taste of a solid core of the pharmaceutical oral solid dosage form" regarding claims 1-6 above. Furthermore, contrary to Applicants' assertion, McCabe teaches making a blend of Opadry White, flavoring agents, and sweetening agents before adding water (column 4, lines 41-63). That blend is a ready mix flavored composition.

Applicants questioned the basis for combining Sue and McCabe to arrive at the claimed contents of the polymer, flavoring agent, plasticizer, and at least one non-soluble additive because McCabe includes a sweetening agent and removing the sweetening agent would result in a different amount of the flavoring agent in the composition of Sue. That is exactly why the Examiner rationalized that the amounts of ingredients in the composition of Sue would have been optimized in order to balance

the flavor of the tablet while masking the odor and taste of the solid core (see rejection above).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HENG M. CHAN whose telephone number is (571)270-5859. The examiner can normally be reached on Monday to Friday, 9:30 am EST to 6:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer K. Michener can be reached on (571)272-1424. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer K. Michener/
Supervisory Patent Examiner, Art Unit 1728

/HENG M CHAN/
Examiner, Art Unit 1728